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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,469	12/04/2000	Anthony P. Heaney	CEDAR-45257	7071

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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 07/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,469

Applicant(s)

HEANEY ET AL.

Examiner

Shin-Lin Chen

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 9-23, 42, 43, 46 and 47, drawn to a method of inhibiting neoplastic cellular proliferation and/or transformation of a mammalian breast or ovarian cell comprising delivering to said mammalian cell a composition comprising a **PTTG-C related polynucleotide** complexed with a cellular uptake agent for treatment of neoplastic proliferation, classifiable in classes 514 and 536, subclasses 44 and 23.5, respectively.
 - II. Claim 8, drawn to a method of inhibiting neoplastic cellular proliferation and/or transformation of a mammalian breast or ovarian cell comprising delivering to said mammalian cell a composition comprising an **antisense oligonucleotide** complexed with a cellular uptake agent for treatment of neoplastic proliferation, classifiable in classes 514 and 536, subclasses 44 and 24.5, respectively.
 - III. Claims 24-41, 44, 45, 48 and 49, drawn to a method of inhibiting neoplastic cellular proliferation and/or transformation of a mammalian breast or ovarian cell comprising delivering to said mammalian cell a composition comprising a **PTTG-C related peptide, or a biologically functional fragment thereof**, complexed with a cellular uptake agent for treatment of neoplastic proliferation, classifiable in classes 514 and 530, subclasses 2 and 300, respectively.
2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I-III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.E.P.. § 806.04, M.E.P.. § 808.01). In the instant case the different inventions have different modes of operation and have different functions. Inventions I-III are distinct because they are drawn to materially distinct methods using different materials that having different chemical structures, different physical properties and different biological functions: polynucleotides or antisense oligonucleotides, and peptides. These methods also differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Method of inhibiting neoplastic cellular proliferation and/or transformation by using a PTTG-C polynucleotide requires different technical considerations and different modes of action than method of inhibiting neoplastic cellular proliferation and/or transformation by using antisense oligonucleotide or peptides. The differences between Inventions I-III are further underscored by their different classification and independent search status. Thus, they are not obvious variants and deemed patentably distinct.

Upon election of an invention, a further restriction is required as follows:

Since the SEQ ID Nos recited in the claims of the present application are derived from different species: SEQ ID Nos. 9 and 10 (human), SEQ ID Nos. 16 and 18 (rat), SEQ ID Nos. 17 and 19 (murine), they represent different and distinct DNA sequences derived from different genes. The chemical structures of different genes are different from each other and their gene

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product functions also differ from each other. Thus, the SEQ ID Nos recited in the claims of the present application are patentably distinct from each other and require separate search. Applicant is required to elect a **single** SEQ ID No. from the group of SEQ ID Nos. 10, 18 and 19 or the group of SEQ ID Nos. 9, 16 and 17 for consideration by examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'Shin-Lin Chen', written in a cursive style.